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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,649	06/04/2002	Pierre Belhumeur	1051-1-019	6750

7590 06/21/2005
Klauber & Jackson
411 Hackensack Avenue
Hackensack, NJ 07601

EXAMINER

BRADRICK, THOMAS DALE

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 06/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,649

Applicant(s)

BELHUMEUR ET AL.

Examiner

Thomas D. Bradrick

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Election/Restrictions

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(i) prion protein degradation indicators transcribed by a gene naturally occurring in a fungus selected from the group consisting of *S. cerevisiae* and *P. anserine*;

prion protein degradation indicators transcribed by a gene selected from the group consisting of SUP35, URE2 and HET-s;

prion protein degradation indicators selected from the group of proteins consisting of Sup35p, Ure2p, Het-s or a combination thereof;

purified prion protein degradation indicators naturally occurring in *S. cerevisiae*, *P. anserine*, a fungus, a recombinant form, an analog, a mutant or a fragment thereof, and;

prion protein degradation indicators that are biological, biochemical or chemical in nature,

(ii) methods of determining prion protein degradation levels carried out by determining the indicator's weight, mass, radical speciation or colorimetric variation or by using radiometry, nephelometry, immuno-enzymatic methods, Western blotting, dot

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blotting, radioimmunology, circular dichroism, electron microscopy, fluorescence microscopy, FTIR, Congo red binding or proteinase digestion,

(iii) efficiency evaluation of a prion protein sterilization processes performed by autoclaving, dry heating or by exposure to chemicals, low temperature plasma gas, ozone or alkylant or oxidizing agents;

efficiency evaluation of a prion protein sterilization processes performed by chemical exposure where the chemical is a vapor or a solution consisting of detergent, ethylene oxide, protease, sodium hydroxide and enzyme;

(iv) efficiency evaluation of a prion protein sterilization process carried out on a degradation indicator in a container consisting of paper, glass, borosilicate, metal, polymer, alloy or composite and

efficiency evaluation of a prion protein sterilization process carried out on a degradation indicator in a container that is porous, permeable or semi-permeable.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Species (i), claims 2-7 and 11, drawn to prion protein degradation indicators;

Species (ii), claim 8, drawn to evaluation or assay methods;

Species (iii), claims 9 and 10, drawn to sterilization processes, and

Species (iv), claims 12 and 13, drawn to containers

The following claim(s) are generic: claims 2-10, 12 and 13.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the sterilization and assay methods and containers are not unique to the use of the claimed invention but can be used (alone or in various combinations) in other functions entirely unrelated to evaluating prion protein degradation.

Applicant is reminded that upon the cancellation of any claims, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for

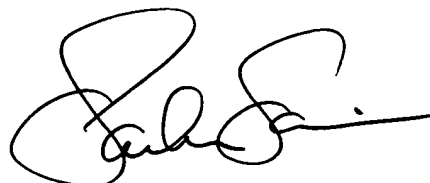
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1651 is M. Wityshyn, (571) 272-0926. The normal work schedule for Examiner Bradrick is 8:30 AM to 6:30 PM Monday through Friday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thomas Bradrick whose telephone number is (571) 272-8139. The number of the Fax Center for the faxing of official papers is (571) 272-8300.



Thomas Bradrick
Patent Examiner
Art Unit 1651
June 17, 2005



SANDRA E. SAUCIER
PRIMARY EXAMINER